JUN - 6 2008

510(k) Summary

Sponsor:	Pioneer Surgical Technology 375 River Park Circle Marquette, MI 49855
Contact Name:	Jonathan M. Gilbert (906) 226-4812
Device Name:	Nerve Monitoring Cable System
Classification:	Panel: Neurology Regulation Number: 882.1350 Regulation Name: Needle electrode Classification Product Code: GXZ
Predicate Device:	K063729 – Disposable Pedicle Screw Probe, Technomed Europe K063305 – Stimulating Bur Guard, Medtronic Xomed K013215 & K002677 – Intraoperative Nerve Surveillance, Nuvasive K062996 & K050194 – Disp. Monopolar and Bipolar Stimulator Probes & Subdermal Needle Electrodes, –, Axon Systems, Inc
Device Description:	This device is intended for use as an intra-operative motor nerve stimulator with common EMG monitors. Construction of the device allows nerve stimulation with general manual orthopedic surgical instruments, e.g. taps, awls, probes, etc. The terminal end of the cable is a 1.5 mm female DIN connector for use with a stimulating consolc with a Type BF or CF rating.
Intended Use:	The Pioneer Nerve Monitoring Cable, in conjunction with Pioneer pedicle probes, taps, awls or screw drivers, is intended to stimulate peripheral motor nerves during surgery for the purpose of locating and identifying these nerves, including spinal nerve roots during the incision and removal of soft and hard tissue or bone.
Material:	Materials used to manufacture the instruments of this system are in conformance with ASTM Standard Specifications.
Basis of Substantial Equivalence:	Comparisons of device performance data, materials, indications and design/function to predicate devices were provided in making a determination of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2008

Pioneer Surgical Technology
% Mr. Jonathan Gilbert
Vice President, Regulatory and Clinical Affairs
375 River Park Circle
Marquette, Michigan 49855-0627

Re: K073229
Trade/Device Name: Nerve Monitoring Cable
Regulation Number: 21 CFR 882.1350
Regulation Name: Needle Electrode
Regulatory Class: Class II
Product Code: GXZ, ETN
Dated: May 27, 2008
Received: May 28, 2008

Dear Mr. Gilbert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.
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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073229

Device Name: Nerve Monitoring Cable

Indications for Use: The Pioneer Nerve Monitoring Cable, in conjunction with Pioneer pedicle probes, taps, awls or screw drivers, is intended to stimulate peripheral motor nerves during surgery for the purpose of locating and identifying these nerves, including spinal nerve roots during the incision and removal of soft and hard tissue or bone.

Prescription Use √ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073229